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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/630,883 | 07/30/2003 | Seth A. Foerster | END 897 DIV1/GSG | 7937 |
| 34263 7590 02/13/2007 O'MELVENY & MYERS LLP 610 NEWPORT CENTER DRIVE 17TH FLOOR NEWPORT BEACH, CA 92660 | | | EXAMINER SZMAL, BRIAN SCOTT | |
| | | | ART UNIT 3736 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | | MAIL DATE | |
| 3 MONTHS | | | 02/13/2007 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/630,883

Applicant(s)

FOERSTER ET AL.

Examiner

Brian Szmal

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/19/06; 11/22/06</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 46 is objected to because of the following informalities: In line 5, "a cavity site" should read as "the cavity site" due to the previous disclosure of "a cavity site" in line 1 of the claim. Appropriate correction is required.
2. Claim 51 is objected to because of the following informalities: In line 1, "The marker" should read as "A marker". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 46-51 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The current specification discloses a radiopaque marker that can be remotely visualized, and also discloses that the marker can comprise a biodegradable polymer. The current specification, however, fails to explicitly disclose: predetermined time periods for which the marker remains at the site; and the use of MRI and ultrasound to detect the marker.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 46-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al (5,411,520).

Nash et al disclose a hemostatic closure means and further disclose a mass of material that is detectable by at least two imaging detection methods; the mass remains at the site for at least a predetermined first time period after the introduction into the cavity and does not interfere with imaging during a predetermined second time period after the first time period; the mass remains imageable for at least the first time period and clears from the site during the second time period; and the marker is detectable by at least two of the following imaging methods: MRI, ultrasound, x-ray, mammography or fluoroscopy. See Column 5, lines 47-52 and 59-62; and Column 6, lines 10-15.

The disclosure of a radiopaque material inherently discloses the ability to remotely image the marker using x-ray and/or fluoroscopy. Furthermore, the ability of the material to degrade in a specified period of time would also inherently disclose the ability to image the site for a first predetermined time and not interfere with imaging during a second time period.

Response to Arguments

7. Applicant's arguments filed November 22, 2006 have been fully considered but they are not persuasive.

The Applicants have traversed the rejections under 35 USC 112, first paragraph, with specific regards to the disclosure supporting: a radiopaque material being detectable using at least two techniques; predetermined time periods for the degradation of the marker; and the use of MRI and ultrasound to detect the marker.

The Examiner agrees with the Applicants argument stating the disclosure supports the marker being detectable using at least two imaging techniques. The radiopaque material does inherently disclose the ability to use x-ray, mammography and/or fluoroscopy to detect the marker, since all three techniques utilize x-rays for imaging. Therefore this rejection has been withdrawn.

The Applicants further argue that the disclosure of "Biodegradable polymers and other plastics could also be used, as long as they are biocompatible, implantable, and visible using an imaging system" inherently discloses the claimed "predetermined time periods". The examiner respectfully disagrees with the Applicants assumption that the claimed matter is inherently disclosed. Based on the dictionary definition of "biodegradable", which is, "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)", as defined in Merriam-Webster's Online Dictionary. The dictionary definition only supports the degradation over an undefined time period, and not a "predetermined time period". Therefore, the rejection is being maintained.

The Applicants further argue that the use of MRI and ultrasound is inherently disclosed, by stating supporting the specification on page 9, lines 16-17; page 3, lines 12-16; and page 6, lines 6-7. The Examiner respectfully disagrees with the Applicants assertion that the disclosure supports the use of MRI and ultrasound. On page 9, lines 16-17, the disclosure supports "radiopaque materials". A "radiopaque" material is defined as "being opaque to various forms of radiation (as X-rays)" as defined in Merriam-Webster's Online Dictionary. Neither MRI nor ultrasound utilize a form of radiation to image. On page 3, lines 12-16, the cited lines pertain to the location of guidewires, as disclosed in Miller et al (5,221,269). Miller et al does not support the utilization of MRI or ultrasound with regards to the current invention. On page 6, lines 6-7, the disclosure supports the use of "using state of the art imaging techniques" for detecting the implanted marker. However, based upon the current specification with regards to using radiopaque materials in the marker for remote imaging, the "state of the art imaging techniques" would only support the use of x-ray, mammography and/or fluoroscopy, as discussed above, and not MRI and ultrasound. Therefore, the rejection is being maintained.

With regards to the prior art rejection of the claims using Nash et al (5,411,520), the Applicants argue that Nash et al fail to disclose a marker for marking a cavity site. The Applicants further disclose the definition of a cavity as "an unfilled space within a mass; especially a hollowed-out space", as defined by www.m-w.com. The Examiner respectfully disagrees with the Applicants argument that Nash et al fail to disclose a means for marking a cavity site. In order to create a puncture tract as shown in Nash et

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al, tissue must be displaced to gain access to the artery or vein. The puncture tract becomes an "unfilled space within a mass".

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BS

M. H. E. Harding